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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,450	03/29/2002	Gilbert Gorr	STURK 0003	9421
24203	7590	10/04/2004	EXAMINER	
GRIFFIN & SZIPL, PC SUITE PH-1 2300 NINTH STREET, SOUTH ARLINGTON, VA 22204			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,450	Applicant(s) GORR ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-16 are pending.

Claim Objections

2. Claims 4, 6, 8-10 and 14-16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claims are drawn to a method for the production of proteins in mosses. Dependent claims 4, 6, 8-10 and 14-16 are drawn to a method for the production of proteins in liverworts. Liverworts are not mosses; mosses and liverworts belong to different Phyla, mosses to the Phylum Bryophyta and liverworts to the Phylum Hepatophyta. Thus, claims 4, 6, 8-10 and 14-16 are broader than the claims upon which they depend.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the production of proteins in *Physcomitrella patens*, does not reasonably provide enablement for a method for the production of proteins in other mosses or in liverworts. The specification does not enable any person skilled in the art to which it pertains,

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or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for the production of proteins in mosses and liverworts, including *Physcomitrella*, *Funaria*, *Sphagnum*, *Ceratodon*, *Marchantia* and *Sphaerocarpos*.

The instant specification, however, only provides guidance for transformation of *P. patens* with a vector encoding vascular endothelial growth factor (VEGF), (pg 14-27).

The instant specification fails to provide guidance for transformation of other mosses or of liverworts.

As the specification does not describe the transformation of any moss or liverwort other than *P. patens* with a heterologous gene, undue trial and error experimentation would be required to develop a transformation method for the other mosses and the liverwort as encompassed by the claims, if transformation is even obtainable.

Given the claim breath and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 4-10 and 13-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 3 and 7 are indefinite in their recitation of “functional fragments thereof”. It is unclear what a functional fragment of a sugar, vitamin or phytohormone would be and what they are functional for.

Claims 4 and 8-10 are indefinite in their recitation of “the group of mosses including liverworts” as liverworts are not mosses. Thus, this is an improper Markush group.

Claims 14-16 are indefinite in their recitation of “the moss tissue is selected from liverworts of the group ...” as liverworts are not mosses. Thus, this is an improper Markush group.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2, 4-5 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Houba-Hérin et al (1999, Plant J. 17:615-626) taken with the evidence of.

Houba-Hérin et al teach a method of producing a heterologous protein in the moss *P. patens*. The protein was a maize cytokinin oxidase and the activity of this enzyme was detected in the culture medium (pg 619, right column, paragraph 1).

Claim Rejections - 35 USC § 103

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houba-Hérin et al (1999, Plant J. 17:615-626) in view of Reutter et al (1996, Plant Tissue Culture and Biotechnol. 2:142-147).

The claims are drawn to a method of producing a heterologous protein in the moss *P. patens*, wherein the moss is grown in media without sugars, vitamins, phytohormones or "functional fragments thereof".

The teachings of Houba-Hérin et al are discussed above. Houba-Hérin et al do not disclose the media in which *P. patens* was grown.

Reutter et al teach that *P. patens* can be grown on inorganic medium (pg 142, paragraph 4).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing a heterologous protein in the moss *P. patens* as taught by Houba-Hérin et al, to use the media described in Reutter et al. One of ordinary skill in the art would have been motivated to do so because choice of culture media is an obvious optimization of design parameters.

11. Claims 1-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Houba-Hérin et al (1999, Plant J. 17:615-626) in view of Nasu et al (1997, J. Ferm. Bioengin. 84:519-523).

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The claims are drawn to a method of producing a heterologous protein in the liverwort of the genus *Marchantia*.

The teachings of Houba-Hérin et al are discussed above. Houba-Hérin et al do not disclose producing a heterologous protein in *Marchantia*.

Nasu et al teach transformation of *Marchantia polymorpha* (pg 520, left column, paragraphs 1-2). *Marchantia polymorpha* is a photoauxotroph, and thus its growth does not require sugars, vitamins, phytohormones or "functional fragments thereof".

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing a heterologous protein in one bryophyte as taught by Houba-Hérin et al, to substitute another bryophyte as described in Nasu et al. One of ordinary skill in the art would have been motivated to do so because substitution of one bryophyte for another is an obvious optimization of design parameters.

12. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeidler et al (1999, J. Plant Physiol. 154:641-650).

The claims are drawn to a method of producing a heterologous protein in the moss of the genus *Ceratodon*.

Zeidler et al disclose transformation of the moss *Ceratodon purpureus* (pg 643-647). *C. purpureus* is grown in media without sugars, vitamins, phytohormones or "functional fragments thereof" (pg 642, left column, paragraph 2). Zeidler et al do not disclose secretion of the encoded protein into the media.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of a method of producing a heterologous protein in the

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Ceratodon as taught by Zeidler et al, to substitute a protein that has the proper signals for secretion. One of ordinary skill in the art would have been motivated to do so because numerous gene products are excreted from the media and Zeidler et al suggests expressing other gene products in *C. purpureus* (pg 649, left column, paragraph 4).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

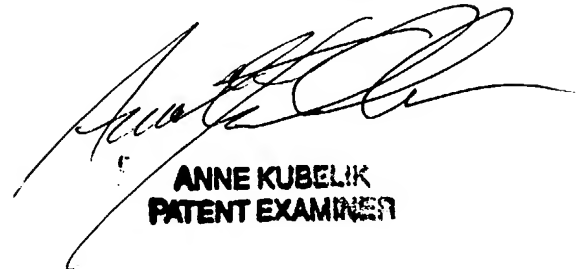
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne R. Kubelik, Ph.D.
September 30, 2004



ANNE KUBELIK
PATENT EXAMINER